1.2% w/w of polybutylphthalate,
4% w/w of isopropanol,
24% w/w acetone, and
ethylacetate up to 100% w/w.

REMARKS

In paragraph 2, on page 2 of the Office Action, the Examiner states that the Oath or Declaration filed is defective because it does not identify the citizenship of the inventor.

Accordingly, Applicant submits herewith a Substitute Declaration and Power of Attorney identifying the citizenship of the inventor.

In paragraph 4, on page 2 of the Office Action, the Examiner rejects Claims 2, 4-6, 8-9, 12 and 19 under 35 U.S.C. § 112, second paragraph.

Specifically, with regards to Claim 2, the Examiner states that the phrase "water soluble compound comprises at least one physiologically active ingredient" is indefinite since a compound is a single chemical structure, and it is unclear how a compound can comprise an active ingredient. The Examiner suggests changing the expression "comprising" to recite "is" to obviate this rejection.

Applicant hereby amends Claim 2 as suggested by the Examiner.

As to Claim 4, the Examiner states that the phrase "composition according to either claim 3 wherein" is indefinite. The Examiner suggests deleting the word "either" to obviate this rejection.

Applicant hereby amends Claim 4 as suggested by the Examiner.

As to Claim 8, the Examiner states that the phrases "phenol derivatives" and "azole derivatives and related compounds" are indefinite.

Applicant hereby amends Claim 8 to delete "phenyl derivatives"; and also amend Claim 8 to substitute the specific compounds listed at page 7, lines 12-16, for "azole derivatives and related compounds".

As to Claims 12 and 19, the Examiner states that the expression "triclosane" is confusing. The Examiner suggests that this rejection can be met by amending the expression "triclosane" to recite "triclosan".

Applicant hereby amends Claims 12 and 19 as suggested by the Examiner.

Accordingly, Applicant respectfully submits that the claims clearly and definitely recite the invention of interest and are enabled by the present specification. Thus, Applicant requests withdrawal of the Examiner's rejection.

In paragraph 11, on page 3 of the Office Action, the Examiner rejects Claims 1-3, 10-11, 13, 15-17 and 20-21 under 35 U.S.C. § 102(b) as being anticipated by Driggers et al.

For the following reasons, Applicant respectfully traverses the Examiner's rejection.

Applicant respectfully submits that Driggers et al does <u>not</u> teach the "water soluble compound" recited in part (c) of Claim 1.

The Examiner is requested to note that in accordance with the present invention, the "at least one water soluble compound" of part (c) of Claim 1 may be a physiologically active ingredient, as defined in Claim 2. A key aspect here is a requirement for "water solubility".

The physiologically active substances described at column 3, lines 3-15 of Driggers et al are all stated to be soluble in the solvent, i.e., soluble in an organic solvent, and not water soluble (see in particular, column 3, lines 8-9 thereof).

The solvent utilized by Driggers et al is described at column 2, lines 38-40 as being a solvent with a low boiling point, preferably less than about 80°C which can completely dissolve the component. Specific examples of these solvents are set out at column 4, lines 48-55, which include acetone, tetrahydrofuran, and methyl ethyl ketone.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Driggers et al, and thus requests withdrawal of the Examiner's rejection.

In paragraph 13, on page 4 of the Office Action, the Examiner rejects Claims 1-21 under 35 U.S.C. § 103 as being unpatentable over Tipton et al in view of Modak et al and Driggers et al.

Specifically, the Examiner states that Tipton et al teaches a biodegradable film dressing and an apparatus for spray delivery of the dressing. Further, the Examiner states that while Tipton et al does not disclose the use of acrylic acid as the film-forming polymer, or chlorbutanol, triclosan, quaternary

ammonium compounds, such as cetrimide, and the specific weight percentages of ingredients of the instant invention; Modak et al teaches a method of inactivating irritants in a fluid contacting skin comprising applying a composition to the skin which contains anti-irritant agents, such as cetrimide, chlorbutanol and triclosan; and Driggers et al teaches the use of acrylic acid in a sprayable composition for forming a bandage on skin. Hence, the Examiner concludes that it would have been obvious to modify the compositions and methods of Tipton et al by use of an acrylic acid in order to benefit from its non-toxic properties, as taught by Driggers et al, and by the use cetrimide, chlorbutanol and triclosan in order to benefit from their anti-irritant properties, as taught by Modak et al.

For the following reasons, Applicant respectfully traverses the Examiner's rejection.

Tipton et al teaches a composition which requires contact with an aqueous fluid to form a film. The aqueous fluid may be added in a separate step, after application of the first polymer composition (see column 2, lines 50-51 thereof). The composition of Tipton et al comprises a liquid composition of at least one biodegradable/bioerodable thermoplastic polymer in a pharmaceutically acceptable solvent (an organic solvent), which may optionally contain a biologically active agent (see column 2, lines 26-31 thereof). Thus, any biologically active agents which are present are dissolved in the solvent, i.e., the organic solvent (see column 2, lines 29-31 thereof). Organic solvents are described at column 6, lines 16-67 thereof and include N-methyl-2-pyrrolidone and alkyl ketones.

Thus, like Driggers et al and Tipton et al does not teach the "water soluble compound" recited in part (c) of Claim 1.

In addition, Tipton et al does not teach a spray-on skin patch composition which, upon application to the skin, forms a flexible, porous and physiologically compatible skin patch when allowed to dry on the skin, as recited in Claim 1.

Tipton et al also does not teach the use of a plasticising agent as described in part (b) of Claim 1. The Examiner's reference to phthalic acid at column 10, lines 56-60 is not understood, as this portion of Tipton et al makes no reference to phthalic esters. The relevant section at column 10, referred to by the Examiner is headed by the words "other additives", at line 35. Such additives are merely optional, and are used for a whole range of purposes, which include increasing cutaneous absorption and to monitor biodegradability. There is no teaching in Tipton et al with respect to using plasticising agents.

Furthermore, the need for contact with an aqueous fluid according to Tipton et al is inconvenient and messy, insofar as an aqueous fluid has to be applied to the skin after application of thermoplastic polymers in an organic solvent, if there is no aqueous fluid in the skin, or present in an amount necessary to form a gel.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Tipton et al, and for the following reasons, it is equally clear that Modak et al and Driggers et al do not provide the deficiencies that exist therein.

Modak et al teaches away from Tipton et al in that it describes compositions for application to a surface, such as skin, which contain an irritant-inactivating agent, in a substance which substantially prevents the irritant-inactivating agent from binding to the surface (see column 2, lines 19-26 thereof). Modak et al does not teach or suggest a non-aerosol spray-on skin patch composition which forms a flexible, porous and physiologically compatible skin patch on drying on the skin, as recited in Claim 1.

The agents cetrimide, chlorbutanol and triclosan, taught at column 4 of Modak et al, are described in the context of irritant-inactivating agents. Modak et al teaches that when irritant-inactivating agents are used, they must be combined with a substance, which is described at column 5, lines 51-65 thereof as being a heavy metal salt, including zinc oxide, zinc carbonate and silver oxide. These heavy metal salts may be included to form a matrix, particularly a gel, as described at column 6, lines 25-44 thereof.

The present invention does not require a substance which substantially prevents the irritant-inactivating agent from binding to a surface, i.e., heavy metal salts.

Modak et al teaches the necessity of including a heavy metal salt in combination with agents, including cetrimide and triclosan. This teaches away from Tipton et al.

Furthermore, a liquid composition which comprises a substantially water-insoluble, non-reactive thermoplastic polymer in an organic solvent is essential to the teachings of Tipton et al. As mentioned above, this liquid composition when

applied to the skin and on contact with an aqueous based fluid, such as an aqueous layer applied after the film dressing (see column 2, lines 50-51 thereof) coagulates to form a microporous or gelatinous matrix. Driggers et al, on the other hand, describes a completely different flexible film coating for application to a mammal based on a polyvinylidine difluoride and copolymers thereof; and α,β-unsaturated carboxylic acid having an acid number of 20 to 150, and a polymer selected from the group including lower alkyl acrylates and methacrylates, and a low boiling salt. This different polymer system teaches away from that of Tipton et al and is incompatible with, and teaches away from, the compositions of Modak et al, particularly zinc salt gels which are required to combine with the irritant-inactivating agents.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Tipton et al, alone or when combined with the teachings of Modak et al and Driggers et al, and in any event, the combination thereof can only be made in hindsight which is legally improper. Thus, Applicant requests withdrawal of the Examiner's rejection.

In view of the amendments to the claims, and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

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A P P E N D I X

Marked-Up Version of Changes

IN THE CLAIMS:

The claims are amended as follows:

Claim 2. (Amended) The composition according to claim 1, wherein the at least one water soluble compound [comprises] is at least one physiologically active ingredient.

Claim 4. (Amended) The composition according to [either] claim 3, wherein the antimicrobial agent is a quaternary ammonium compound.

Claim 8. (Amended) The compound according to [any one of claims] claim 7, wherein the antimicrobial agent is a quaternary ammonium compound and the antifungal agent is selected from chlorbutanol, phenol, [phenol derivatives,] salicylic acids, arisoran, amoralfine, amphotericin, [azole derivatives and related compounds,] bifonazole, butoconazole nitrate, chlormidazole, clotrimazole, croconazole, econazole, enilconazole, fenticonazole, fluconazole, flutrimazole, isoconazole, itraconazole, ketoconazole, lanoconazole, miconazole, omoconazole, saperconazole, sertaconazole, sulconazole, terconazole, tioconazole, benzoyl disulphide, bromochlorosalicylanilide, buclosamide, butenafine, candicidicaprylic acid, chlorphenesin, ciclopirox olamine, cilofungin, fenticlor, flucytosine, criseofulvin, hachimycin, haloprogin, hamycin, hydroxystilbamidine, isethionate, loflucarban, mepartricin, natamycin, nifuroxime, p-nitrophenol, nystatin, pentamycin, propionic acid, protiofate, pyrrolnitrin, sulbentine, terbinafine, tolciclate, tolnaftate, triacetin, and undecenoic acid.

Claim 12. (Amended) The composition according to claim 11, wherein the at least one physiologically active ingredient is [tricolsane] triclosan.

Claim 19. (Amended) The composition according to claim 18 comprising:

0.05% w/w or [centrimide] cetrimide,

0.07% w/w of [triclosane] triclosan,

0.6% w/w of chlorbutanol,

10% w/w or polymethacrylic acid,

1.2% w/w of polybutylphthalate,

4% w/w of isopropanol,

24% w/w acetone, and

ethylacetate up to 100% w/w.